# UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

PAR PHARMACEUTICAL, INC., PAR STERILE PRODUCTS, LLC, and ENDO PAR INNOVATION COMPANY, LLC,

AMENDED OPINION

Plaintiffs,

v.

Civ. No. 16-02290 (WHW)(CLW)

LUITPOLD PHARMACEUTICALS, INC., DAIICHI SANKYO, INC., and DAIICHI SANKYO COMPANY, LTD.,

Defendants.

Walls, Senior District Judge

The facts of this case are more fully recounted in the Court's January 18, 2017 Opinion granting Defendant's motion for judgment on the pleadings under Fed. R. Civ. P. 12(c). ECF No. 105. In short, this case arises out of a patent dispute between Plaintiffs Par Pharmaceutical, Inc., Par Sterile Products, LLC, and Endo Par Innovation Company, LLC (collectively, "Par" or "Plaintiffs"), and Defendants Luitpold Pharmaceuticals, Inc., Daiichi Sankyo, Inc., and Daiichi Sankyo Co., Ltd ("Defendants"). Par is the assignee of several patents for Adrenalin®, a product containing 1 mg of the active ingredient epinephrine, which is used primarily to treat allergic reactions. Am. Compl., ECF No. 70 ¶¶ 34–39. In early 2016, Defendant Luitpold filed an Abbreviated New Drug Application ("ANDA") with the Food and Drug Administration ("FDA"), which sought approval to market a generic version of Par's Adrenalin® product. *Id.* ¶ 46. By letters dated March 9, 2016 and July 7, 2016, Luitpold submitted to Par notices of certification under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95(c) regarding its proposed

generic epinephrine product as specified in its ANDA. *Id.* ¶¶ 47–50. Par then initiated this suit under the Drug Price Competition and Patent Term Restoration Act (the "Hatch-Waxman Act"), asserting that Luitpold's ANDA submission constituted an act of infringement of their patents and seeking a declaration that Luitpold's Future Generic Product – the drug to be marketed and sold after FDA approval – would infringe Par's patents. *Id.* ¶¶ 65–80. Luitpold's Answer to Par's Complaint denied infringement and asserted four counterclaims. ECF No. 13. Luitpold sought declaratory relief that it had not and was not infringing Par's Adrenalin® patents; that the Patents-in-suit were invalid under 35 U.S.C. § 101; that Luitpold was entitled to a defense to infringement based on earlier commercial use, and that the case was exceptional under 35 U.S.C. § 285. *Id.* ¶¶ 115–118.

On September 9, 2016, Luitpold filed a motion for judgment on the pleadings, ECF No. 41, which the Court granted on January 18, 2017, ECF No. 105. The Court dismissed Plaintiffs' patent infringement claims with prejudice and granted Luitpold's counterclaim seeking a declaratory judgment of non-infringement because, as Par admits, Luitpold's current ANDA formulations do not infringe Par's Adrenalin® patents. ECF Nos. 105–06, 119–20. The Court also dismissed Par's claims under the Declaratory Judgment Act without prejudice as unripe, finding they were "premised on speculation that future, uncertain amendments to Luitpold's ANDA will infringe Par's patents." ECF No. 105 at 14; ECF Nos. 119–20. In the Court's March 8, 2017 Order amending the Court's January 18, 2017 Order granting Luitpold's motion for judgment on the pleadings, the Court also dismissed Luitpold's Second and Third Counterclaims without prejudice at Luitpold's request. ECF No. 120.

Defendants moved for attorney fees under 35 U.S.C. § 285 on February 21, 2017. ECF No. 112. Defendants argue that they are prevailing parties under 35 U.S.C. § 285, that the case

should be considered exceptional, and that the Court should exercise its discretion to award fees because (1) "Par asserted an objectively baseless theory of infringement"; (2) "Par knew its allegations were false before filing suit"; (3) The Complaint improperly joined the Daiichi Sankyo Defendants" (4) Par abused discovery to attempt to monitor Defendants' competitive activities"; and (5) the case "violates public policy favoring prompt resolution of Hatch-Waxman cases." ECF No. 128 at 4–9. Par responds that "Luitpold is not the prevailing party with respect to Par's claims based on Luitpold's Future Generic Product" and that Par's case against Luitpold is not exceptional because (1) Par had reason to believe Luitpold would change its drug formulation; (2) Par's legal positions were neither objectively baseless nor inconsistent with case law; (3) Par's allegations were never false; (4) the Complaint properly joined all Defendants; (5) Par did not abuse discovery and received almost no substantive discovery in the case; and (6) Par's case does not violate the public policy underpinning Hatch-Waxman cases. ECF No. 116 at 14–26.

#### LEGAL STANDARD

35 U.S.C. § 285 authorizes courts to award reasonable attorney fees to the party prevailing in patent litigation in an "exceptional case." To satisfy the statute, Defendants must establish: (1) they are the prevailing party; (2) the case is exceptional; and (3) the fees are reasonable. *Machinery Corp. of America v. Gullfiber AB*, 774 F.2d 467, 471 (Fed. Cir. 1985). Defendants bear the burden to establish the exceptional nature of the case by a preponderance of the evidence. *Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, 134 S. Ct. 1749, 1758 (2014).

"[A]n 'exceptional' case is simply one that stands out from others with respect to the substantive strength of a party's litigating positions (considering both the governing law and the facts of the case) or the unreasonable manner in which the case was litigated." *Id.* at 1756.

Exceptionality is determined by courts "in the case-by-case exercise of their discretion, considering the totality of the circumstance." Id. An award of fees may be justified where a case "present[s] either subjective bad faith or exceptionally meritless claims," or where a party has engaged in misconduct, whether or not that conduct is independently sanctionable. *Id.* at 1757. In assessing the totality of the circumstances, courts can consider "nonexclusive factors," including "frivolousness, motivation, objective unreasonableness (both in the factual and legal components of the case) and the need in particular circumstances to advance considerations of compensation and deterrence." Id. at 1756 n.6 (citing Fogerty v. Fantasy, Inc., 510 U.S. 517, 534 n.19. (1994)). While "there is no precise rule or formula" for determining if a case is exceptional, Octane Fitness, 134 S. Ct. at 1756, "fee awards are not to be used 'as a penalty for failure to win a patent infringement suit." Gaymar Indus., Inc. v. Cincinnati Sub-Zero Prods., Inc., 790 F.3d 1369, 1373 (Fed. Cir. 2015) (citations omitted). Even if a district court determines that a case is exceptional, it remains within the court's discretion to deny a fee award based on its familiarity with the matter and the interest of justice. Icon Health & Fitness, Inc. v. Octane Fitness, LLC, 576 F. App'x 1002, 1005 (Fed Cir. 2014).

# **DISCUSSION**

# A. Defendants are prevailing parties

The Court granted Luitpold's motion for judgment on the pleadings, resulting in the dismissal of Counts I and III of Par's Amended Complaint with prejudice, the dismissal of Counts II and IV of Par's Amended Complaint without prejudice for lack of ripeness, and a declaration that Luitpold has not and is not now infringing Par's '876 and '657 patents. ECF No. 120. All claims against the Daiichi Sankyo Defendants are based upon claims that Luitpold's Abbreviated New Drug Application constitutes an act of infringement of Plaintiffs' Orange Book

listed patents, Compl., ECF No. 70 ¶ 65-80. The Order granting Luitpold's motion for judgment on the pleadings, ECF No. 120, is also dispositive for all of Par's claims against Daiichi Sankyo, Inc. and Daiichi Sankyo Co., Ltd. Because Defendants "receive[d] at least some relief on the merits, which alter[ed] the legal relationship of the parties," they are prevailing parties under 35 U.S.C. § 285. *Inland Steel Co. v. LTV Steel Co.*, 364 F.3d 1318, 1320 (Fed. Cir. 2004) (quoting *Former Employees of Motorola Ceramic Prods. v. United States*, 336 F.3d 1360, 1364 (Fed. Cir. 2003) (internal quotation marks omitted)).

# B. The case is exceptional

Defendants argument that the case is exceptional is primarily based on their contention that Par's legal theory was baseless and that "Par abused discovery to attempt to monitor Defendants' competitive activities." ECF No. 128 at 4–8. Defendants contend that Par asserted an objectively baseless theory of litigation because "no reasonable litigant' in Par's shoes 'could reasonably expect success on the merits'" ECF No. 128 at 4 (citing *Highmark, Inc. v. Allcare Health Mgmt. Sys., Inc.*, 687 F.3d 1300, 1309 (Fed. Cir. 2012)). Defendants urge that Par abused the discovery process by pushing ceaselessly for highly competitive business information unrelated to the issues in the case, including filing a motion to compel during the pendency of Luitpold's motion for judgment on the pleadings, and after Luitpold's director of R&D provided testimony that Luitold had never tested a drug formulation including a bisulfite antioxidant and had no plans to do so. ECF No. 128 at 8–9. Par answers Defendants by stating that it "had good reason to bring the lawsuit" because it believed Luitpold "would change its formulation," to infringe Par's patents, ECF No. 116 at 6–7, and that Par did not abuse discovery because it received virtually no "substantive discovery." *Id.* at 25–26.

Plaintiffs have consistently maintained in briefing throughout this case that their primary concern is that Defendants will seek and receive FDA approval for an epinephrine product that infringes their '876 and '657 patents. See, e.g., ECF No. 116 at 17 ("Thus, the key question in Par's case—and the question that helps to determine whether future infringement is 'immediate' and 'real'—was how Luitpold intended to obtain FDA approval of its generic version of Par's ADRENALIN®."). But contrary to this stated purpose, Plaintiffs' Complaint and Amended Complaint alleged, without any factual basis, that Defendants' current ANDA infringed the patents-in-suit. See ECF No. 1 ¶¶ 62–65, 70–73; ECF No. 70 ¶¶ 65–68, 73–76. While Plaintiffs repeatedly argued that it only alleged current patent infringement to trigger Hatch-Waxman review of "the product that Defendant Luitpold will likely market if its ANDA receives final FDA approval," ECF No. 70 ¶ 53, the Court found that Par's legal theory was completely unsupported by case law and ignored the existing legal safeguards against Defendants' potential future infringing conduct,1 ECF No. 105. See In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig., No. CIV. 09-MD-2118-SLR, 2012 WL 95592, at \*2 (D. Del. Jan. 12, 2012) (finding a patent case "exceptional" under 35 U.S.C. § 285 when plaintiffs agreed that defendant's product, as formulated in its ANDA, did not infringe, but insisted on maintaining the suit to "police" against possible reformulations). Moreover, in response to Luitpold's First Counterclaim, which sought a declaration that Luitpold had not and was not currently infringing the patents-in-suit. Par refused to admit non-infringement of Luitpold's operative ANDA. ECF No. 39 ¶ 115.

<sup>1</sup> When an ANDA filer makes an alteration or amendment to its application, for example, by changing the drug's formula, the FDA requires ANDA filers to provide a new Paragraph IV Certification and re-notice the patent holder and drug owner. See, e.g. Ben Venue Labs., Inc. v. Novartis Pharmaceutical Corp., 146 F. Supp. 2d 572, 580–81 (D.N.J. 2001); Paddock Labs., Inc. v. Ethypharm S.A., Civ. No 09–3779, 2011 WL 149860, at \*3 (D.N.J. Jan. 18, 2011); see also 21 C.F.R. §§ 314.96(d).

Even if Par's intention was limited to anticipated patent infringement by a possible future formulation of Luitpold's product, Par's claims were meritless because Par provided no basis for its allegations that absent declaratory relief, Par faced irreparable harm from Defendants' infringing activities. Par's claims for declaratory relief rested only on its own experience of the FDA approval process and speculation that the FDA would require Defendants to change their drug formulation in a manner that would infringe Par's patents. ECF No. 70 ¶¶ 69–72, 77–80. Par failed to allege that Defendants were engaged in any specific activities to alter their drug formulation to infringe the patents-in-suit and even acknowledged in briefing that the focus of the case was to determine through discovery how Par intended to proceed through the FDA approval process. *See* ECF No. 116 at 17. Ultimately, the absence of credible allegations or evidence that Par would face immediate, irreparable harm absent declaratory relief, caused the Court to conclude the declaratory judgment counts were "not ripe for adjudication." ECF No. 108 at 2.

Finally, upon filing of the Complaint, Par vigorously attempted to engage in overbroad discovery of highly confidential, competition information. Despite having a complete copy of Luitpold's ANDA and assurances that Defendants were complying with Local Patent Rule 3.6(j) and turning over all new communications to and from the FDA within seven days, Par requested (1) all documents and information relating to Defendants' injectable epinephrine compositions, including past, current, and "contemplated" formulations whether or not they contained ingredients that would infringe Par's patents, including business development documents, ECF No. 128 Ex. C, RFP Nos. 2–8, 12, 27 and Interrogatory No. 4; (2) all "research, development, formulation, design, testing, manufacture, quality control, production, studies, or evaluations" without regard to whether the epinephrine products contained the bisulfite antioxidant used in the

patents-in-suit, *Id.* at RFP Nos. 3, 6–7, 30 and Interrogatory No. 5; (3) "all documents reflecting Luitpold's criteria, policies, or practices for selecting products for which it files ANDAs," *Id.* at RFP No. 25; and (4) "market data, meeting minutes, guidelines, and regulatory plans" and "all analyses/ projections of the epinephrine market," *Id.* at RFP Nos. 13, 24. Par pursued this overbroad information by a motion to compel discovery, ECF No. 85, even after Luitpold's director of R&D responded to one of Par's interrogatories by swearing Luitpold had not changed its drug formulation, had not added any antioxidant, and had not conducted any testing using sodium bisulfite or any other bisulfite component, ECF No. 128 Ex. D, Luitpold's Response to Par's Third Set of Interrogatories, Interrogatory No. 5. Par's conduct is not mitigated by Par's argument that it pursued this discovery mostly unsuccessfully.

For these reasons, the Court finds the case to be "exceptional" within the meaning of 35 U.S.C. § 285. Plaintiffs' unjustified maintenance of this suit and attempts to use discovery to police Defendants' future conduct makes an award of fees appropriate to the extent Defendants' fee request is reasonable.

# C. Defendants' fee request is reasonable

Par did not argue that Defendants seek unreasonable fees; however, the amount of a fee award is assessed at the discretion of the district court. *See Lumen View Tech. LLC v. Findthebest.com*, Inc., 811 F.3d 479, 483 (Fed. Cir. 2016). "In determining the reasonableness of the award, there must be some evidence to support the reasonableness of, inter alia, the billing rate charged and the number of hours expended." *Lam, Inc. v. Johns-Manville Corp.*, 718 F.2d 1056, 1068 (Fed. Cir. 1983). Local Civil Rule 54.2 governs fee awards, and requires the party seeking fees to provide certain materials to the Court, including affidavits setting forth the nature of services rendered, a record of the dates and times of services rendered, a description of the

services rendered on each date, a description of the professional experience of each person rendering services, the normal billing rate for each person rendering services, any fee agreements, and the amounts actually billed to the client and paid by the client. See L.Civ.R. 54.2(a)–(b). In the 35 U.S.C. § 285 context, Courts generally consider hourly time records and expense statements along with documentation in support of the movant's billing rates as compared with those prevailing in the community for similar work, taking into account the attorneys' skill and experience. See Source Search Techs., LLC v. Kayak Software Corp., No. 11-3388(NLH/KMW), 2016 WL 1259961, at \*9 (D.N.J. Mar. 31, 2016). The party seeking an award of fees has the burden to provide evidence supporting the hours worked and rates claimed. Hensley v. Eckerhart, 461 U.S. 424, 434 (1983). To the extent the affidavits and supporting documentation submitted by the party seeking fees "leaves any doubt as to the amount of fees to be awarded, these doubts shall be resolved against an award of fees." Spectrum Produce Distributing, Inc. v. Fresh Marketing, Inc., Civ No. 11-06368 (JBS/KNW), 2012 WL 2369367, at \*3 (D.N.J. June 20, 2012) (quoting Veneziano v. Long Island Pipe Fabrication & Supply Corp., 487 F. Supp. 2d 683, 695 (D.N.J. 2002)).

### 1. Calculation of Fees

The Court begins its determination of a reasonable attorneys' fee award by calculating the lodestar amount. *Penn Env't Def. Found. V. Canon-McMillan Sch. Dist.*, 152 F.3d 228, 231 (3d Cir. 1998). The lodestar is the "number of hours reasonably expended on the litigation multiplied by a reasonable hourly rate." *Hensley*, 461 U.S. at 433. The Court first determines the appropriate hourly rate for the services rendered. "To show the reasonableness of a requested rate, counsel must produce satisfactory evidence — in addition to their own affidavits — that the requested rates are in line with those prevailing in the community for similar services by lawyers

of reasonably comparable skill, experience, and reputation." *Spectrum Produce*, 2012 WL 2369367, at \*4 (internal modifications omitted) (quoting *Blum v. Stenson*, 465 U.S. 886, 896 n.11 (1984)).

# a) Hourly Rate

Defendants submitted billing records that show that nine different individuals performed work on this matter. ECF No. 130. The rates Defendants seek for the work performed on this case range from \$215/ hour to \$950/ hour. ECF No. 134-1. Defendants also submitted a declaration from Howard P. Janis ("Janis Declaration"), Director of Strategic Pricing and Analytics at Defendants' law firm, Dentons, which states that the billing records reflect time worked on the case by attorneys and paralegals. ECF No. 130 ¶ 10. Defendants provided the Court with biographies of the attorneys. Long Decl., ECF No. 129 Ex. 2. Only four biographies were provided. *See id*. Because no information was provided about the five remaining time keepers, the Court used the billing records to determine the type of work each contributed.

To establish the prevailing rate for this type of litigation, Defendants refer to excerpts from PricewaterhouseCoopers' Billing Rate and Associate Survey Salary ("BRASS Report") for peer IP litigation firms. *See* Janis Declaration, ECF No. 130 Ex. 1. This data reveal that Dentons' associate rates rank near the bottom of peer IP litigation firms, but that its partner rates venture into the first quartile of IP litigation rates. *Compare id. with* ECF No. 134-1. The Court finds that \$925/ hour is unreasonable, especially in light of the fact that much of the work charged at this rate consisted of reviewing others' work product and tending to emails. *See* ECF No. 134-1. The documentation shows that most of the work performed on this matter was billed by attorneys at an hourly rate between \$300 and \$800. *Id.* The Court will therefore award fees at a rate of \$550/ hour for all attorney work credited by the Court based on the invoices submitted by Defendants.

Finally, the BRASS Report only provides evidence of attorney billing rates. *See* ECF No. 130 Ex. 1. Because Defendants submitted no documentation justifying a paralegal rate, the Court awards fees at a rate of \$125/ for all work it has identified as the kind typically performed by paralegals. *See U.A. Local 322 Pension Fund v. J.R. McGee Plumbing Ltd. Liab. Co.*, No. CV 16-3738 (RMB/KMW), 2017 WL 498692, at \*4–5 (D.N.J. Feb. 7, 2017) (awarding attorney fees for paralegal work at the hourly rate of \$125).

# b) Time Reasonably Expended

The Court next determines how much time was reasonably expended on the matter. *Public Interest Research Group of N.J., Inc. v. Winall*, 51 F.3d 1179, 1188 (3d Cir. 1995). To establish the reasonableness of the time spent litigating this matter, Defendants', at the Court's request, submitted unredacted invoices, containing a narrative description of each task performed. ECF No. 134-1. Defendants request compensation for 485.4 hours of work. *Id.* The Court has determined that 66.1 of the requested hours constitute tasks typically performed by paralegals, such as compiling documents for attorney review, updating case files, researching local filing rules, and preparing motion exhibits. *See id.* The invoices establish that the remaining 419.3 hours reflect attorney work. See *id.* Though a majority of the requested hours was reasonable, the Court finds Defendants' billing unreasonable in part and reduces the hours total to 55.4 hours of paralegal work and 364.65 hours of attorney work.

The Court finds Defendants' billing unreasonable to the extent it includes hours incorrectly billed to this matter, hours billed for unnecessary tasks, hours billed due to inexperience, and hours billed for tasks that should have been performed by specialized or more cost-effective actors. *See Spectrum Produce*, 2012 WL 2369367, at \*5–10. Defendants state in a letter to the Court that the invoices submitted for the Court's review include 14.4 incorrectly

billed hours from the July billing period. ECF No. 134. The Court finds that 13.6 of these hours are attorney work hours and .8 are paralegal work hours. Additionally, the Court's review revealed that a number of Defendants' June and July invoices refer to work performed in an Eastern District of New York case involving the same parties. *See* ECF No. 134-1. Where these invoices referred solely to work for the parallel case, the Court struck the requested hours. Where the invoices made clear that work was performed in both cases, the Court reduced the hours by half. In total, the Court reduced the requested paralegal hours by 7.4 and the attorney hours by 2.25 based on the time-keeper references to work performed for the E.D.N.Y. case.

Courts in this district have held that attorneys cannot bill for work product that was not considered by the Court. See T.B. v. Mount Laurel Bd. Of Educ., No 09-4780, 2012 WL 1079088 (D.N.J. Mar. 30, 2012). Defendants' invoices reflect work performed in August 2016 for a motion to dismiss, work completed in September and October related to an FTO opinion and "prior art chart," and research performed in November concerning "first to file exclusivity" and an extraneous patent number. See ECF No. 134. Defendants did not raise the factual or legal issues reflected in these billing narratives before the Court. As such, the Court reduces the attorney work hours by 23.2 and the paralegal hours by 2.4 to account for time spent on these tasks. See id.

Finally, the Court does not award attorneys' fees for time billed due to inexperience, and for tasks that should have been performed by specialized or more cost-effective actors.

Defendants' invoices reflect 1.9 paralegal hours spent setting up ECF notifications and .2 attorney hours for supervising the filing of requests for ECF notifications in September 2016. See id. The Court awards no fees for the extraordinary amount of time spent filing a form letter with the Court. The invoices also reflect 1.8 attorney hours spent preparing and serving courtesy

copies and supervising the filing of a consent Order in September 2016. See id. The Third Circuit has held that it is unreasonable for an attorney to claim an attorney reimbursement rate for tasks that could be effectively performed by less expensive individuals. Loughner v. University of Pittsburgh, 260 F.3d 173, 180 (3d Cir. 2001). These tasks are more properly performed by a paralegal, or by an attorney at a paralegal rate. Therefore, the 1.8 hours billed in September 2016 for filing and preparing courtesy copies will be billed at the \$125/ hour rate previously set forth for paralegal work.

Applying the rules articulated above, the Court awards Defendants \$200,557.50 in fees for attorney hours and \$6,925 in fees for paralegal hours for a lodestar total of \$207,482.50.

2. Award of Costs

Defendants further petition the Court for \$4,580.93 in costs expended in the delivery of service and documents, payment of filing fees, travel to an in-person hearing, and necessary document reproduction. *See* ECF No. 134. These costs were all rendered necessary by the nature of this litigation and the Court finds them to be reasonable. The Court awards Defendants their requested costs of \$4,580.93.

CONCLUSION

Defendants' Motion for Attorney Fees, ECF No. 112, is granted in the reduced amount of \$207,482.50 in fees and \$4,580.93 in costs. An appropriate order follows.

DATE: 24 April 2017

William H. Walls

Senior United States District Court Judge